Exhibit 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Master Case No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory Case No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	

REPLY MEMORANDUM OF UNITED STATES IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF W. DAVID BRADFORD, PH.D AND REQUEST FOR EVIDENTIARY HEARING

In its Opposition to the United States' motion to exclude certain opinions of Dr. Bradford, Dey fails to explain how Dr. Bradford's opinions relate to any element of the False Claims Act, or to demonstrate that Dr. Bradford's opinions have a reliable, non-speculative basis. Instead, Dey's brief is largely an exercise in evasion, devoting pages to Dr. Bradford's qualifications and descriptions of portions of his report that are not at issue, yet failing to meaningfully respond to the substance of the government's motion.[1]

I. Dr. Bradford's Medicare Opinions

A. Dr. Bradford's Opinion That Lawmakers Could Have Used WAC

Plaintiffs challenge Dr. Bradford's opinion that Congress "could have made use of the WAC that Dey made available . . . and chose not to use it," Bradford Report ("Report") at 121, and his "adjustment" of Dr. Duggan's damages calculations to show that damages are reduced to

[1] The instant motion focuses on the most glaring of Dr. Bradford's opinions. Many parts of Bradford's report that are not specifically mentioned in the government's motion become irrelevant if the motion is allowed. At trial, the United States expects to object to and seek to exclude many additional opinions or statements of Dr. Bradford.

zero if one assumes Dey is not responsible for the spread between its WACs and AWPs because Medicare could have used Dey's WACs as the basis for payment. *Id.* at pp. 141-143.[2] In defense of this proffered testimony, Dey simply asserts that "Dr. Bradford accepts the law as given," and that "this opinion is admissible" because the "point is an economic one directed toward the existence of other known pricing points." Dey Mem. 13-14. This is nonsense. First, Dr. Bradford's analysis, which invites the jury to speculate that Dey would have caused *no* damages if only the laws and regulations governing Medicare had been different, does the *opposite* of "accept the law as given."

Second, the fact that Dr. Bradford's "point is an economic one" does not make it admissible. For expert testimony to be admissible, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Ev. 702. Dey suggests Dr. Bradford's testimony is relevant to scienter, Dey Mem. 14, but fails to explain how an opinion that Medicare "could have made use of the WAC . . . and chose not to" has any bearing on the "knowledge" element of the False Claims Act. The opinion that Medicare "could have used WAC" (and would not have suffered damages if it did) should be excluded as irrelevant and misleading.

B. Dr. Bradford's Pre-MMA and Post-MMA Comparisons

In its Opposition, Dey acknowledges for the first time that the charts and associated analysis presented at pp. 117-120 the Report, which purport to show allowed drug cost payments

[2] Dr. Bradford also proposes alternative damages calculations based on the unfounded assumption that Medicare payments must be high enough to ensure that the "marginal pharmacy," i.e., the pharmacy that pays at the 95th percentile of drug acquisition costs, will make a profit. This opinion suffers from the same flaw discussed in Part II.B of the government's principal brief. There is nothing to support the conclusion that Medicare intended to pay at the 95th percentile of pharmacy acquisition costs. *See* Memorandum in Support of United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D (Master Doc. #6914, Sub. #693) ("U.S. Mem.") at 17 n.18.

and dispensing fee payments in 2004 and 2005, relate entirely to transition years post-dating the damages period, specifically 2004, when the drug cost payment was 80 percent of AWP, and 2005, when a transitional one-year dispensing fee was in effect. Dey Mem. 11.[3] Rather than explain how either year is relevant, Dey simply asserts the issue "is properly left for cross-examination." *Id*. This response ignores the fact that Dey has the burden of establishing its admissibility. *See Jesionowski v. Beck,* 955 F. Supp. 149, 150 (D. Mass. 1997) ("proponent of the evidence has the burden of demonstrating that the expert is going to testify to 'scientific knowledge'") (*quoting Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 590 (1993)); Fed. R. Evid. 702 advisory committee's note (proponent "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence").

Dr. Bradford's report (which does not even acknowledge that 2004 and 2005 were transitional years) fails to explain the relevance of Medicare's payments in those atypical years to any element at issue in this case – causation, falsity, Dey's knowledge of the falsity, materiality, or damages. The evidence did not even exist during the relevant time period and, as Dey concedes, neither the drug cost payment amount during 2004 nor the dispensing fee for 2005 could reasonably be used as a basis for anyone's "but for" world.[4]

---

[3] The final, non-transitional dispensing fee for inhalation therapy drugs became effective January 1, 2006. 70 Fed. Reg. 70116, 70334 (Nov. 21, 2005).

[4] Dey suggests that the chart relating to cromolyn sodium (Figure 33) is relevant because the United States has not foresworn a claim for civil penalties. Not only is this information irrelevant to a determination of civil penalties, the issue of civil penalties is *not even one properly put to the jury*. *See United States ex rel. Miller v. Bill Harbert Intern. Const., Inc*., 2007 WL 851868 (D.D.C. 2007) ("The application of statutory penalties and trebling of damages are mechanical actions for the Court alone.").

Dey's defense of Figure 34, which is based on a HCPCS code (J7616) for a brand drug that is not part of this case (DuoNeb®), is particularly puzzling. Dey claims the chart is admissible because:

> there was an off-setting pattern of utilization due to the introduction of the new J-Code J7616. Examining this type of behavioral response to policy changes is the province of a health care economist, and a relevant analysis for an economics expert.

Dey Mem. 12. Again, simply claiming that a particular type of analysis is within the province of a health care economist does not make it admissible. *See Daubert at* 591-592 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."). Figures 33 and 34 are clearly designed to mislead the jury into thinking that the MMA left the "total payment rate for inhalation drugs the same" (*see* Report at p. 120 (¶ 257)), when, in fact, available evidence indicates that the switch to ASPs caused per-prescription spending to decline significantly. *See* April 23, 2009, Rebuttal Report of Mark G. Duggan, Ph.D, 13 - 16. In any event, Dr. Bradford has not provided any reliable basis for opining that the MMA left the total payment for inhalation drugs the same. The Court therefore should exclude the charts and associated analyses as irrelevant and unreliable.

C. Dr. Bradford's Medicare "Dispensing Fee Shortfalls"

A central theme of the Report is that, "when reimbursement is based on a lower price, such as ASP or Dr. Duggan's average prices, it is necessary to increase the total reimbursement to providers by increasing the dispensing fee. It is not possible to subtract from the ingredient side without adding something to compensate for an inadequate $5 dispensing fee." Dey Mem. 10; Report ¶¶ 239-240. Dr. Bradford and Dey, however, leave the United States and the Court to guess the elements of the False Claims Act to which this opinion is supposed to be relevant. As

explained in greater detail below, Dr. Bradford's opinion that ingredient cost reimbursement cross-subsidized low dispensing fees – and that Medicare would have raised dispensing fees had Dey reported lower AWPs – is too speculative to survive this Court's gate-keeping function, and it does not bear on any element of liability or damages under the FCA.[5]

1. Dr. Bradford's Testimony Is Irrelevant to Any Element of Liability

First, whether Medicare cross-subsidized for low dispensing fees does not make it any more or less probable that Dey's reported AWPs, and the resulting provider claims, were "false." To the extent Dey suggests otherwise, this argument has been resolved by this Court's and the First Circuit's ruling that the term "average wholesale price" is properly construed according to its plain meaning.[6] Second, Dr. Bradford's cross-subsidization opinion is not relevant to whether Dey "caused" false claims to be presented for payment. If the Court rules, as it should, that Dey's AWPs and the provider claims based on those AWPs were false, there can be no doubt that Dey "caused" the false claims to be submitted. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 144-145 (D. Mass. 2008) ("The defendants are thus chargeable with causing false claims to be presented to the Commonwealth."); *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255 (D. Mass. 2003). If Dey means to suggest that the government "caused" the false claims to be submitted, this argument should be rejected

[5] If, as suggested by Dey, Dr. Bradford "is simply critiquing Dr. Duggan's methodology" (Dey Mem. 11), then his Medicare opinions apply only to damages as that is all that Dr. Duggan addresses. In an excess of caution, the United States also explains why Dr. Bradford's opinion have no bearing on any element of Dey's Medicare liability under the FCA.

[6] *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277 (D. Mass. 2006), *aff'd*, 582 F.3d 156, 171 (1st Cir. 2009).

outright, as it turns the concept of causation on its head. The government neither reported the inflated AWPs nor directed Dey to do so.

To the extent Dey asserts that the government's failure to change its reimbursement formula constitutes an "intervening cause" negating causation, any such suggestion is meritless. "Under black letter law . . . an intervening force only breaks the causal connection when it is unforeseeable." *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255 (D. Mass. 2003). Dey cannot show that government action and/or inaction in failing to prevent the harm was unforeseeable. On the contrary, Medicare's continued use of Dey's reported AWPs was exactly what Dey expected. In any event, even if the government's failure to prevent harm were unforeseeable, it could not constitute an intervening force absolving a defendant unless there exist extraordinary circumstances shifting all legal duty to prevent the harm to the plaintiff. Restatement (Second) of Torts § 452. Here, where Dey's false reporting, and its duty to report truthfully, continued throughout the relevant time period, Dey cannot possibly present a factual issue for the jury regarding an intervening cause.

Finally, Dr. Bradford's opinions do not make a finding of materiality more or less probable. As a matter of law, Medicare reimbursed for Part B drugs based on AWP, and consequently a false AWP had a natural tendency to affect Medicare's payments. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d at 153 ("Reporting false WACs had a natural tendency to influence the Commonwealth's actions, by inflating the amounts used to compute EAC, and thus potentially the amount of the Commonwealth's payment. There is no genuine issue as to the materiality of the defendants' false statements when they reported WACs."). No amount of expert opinion about cross-subsidization can change this result.

Therefore, if Dr. Bradford's opinions regarding cross-subsidization have any relevance, it can only be to the issue of damages. As explained below, the opinion that damages should be offset because Medicare would have increased dispensing fees if Dey reported lower AWPs is simply too speculative to be admissible.

2. Dr. Bradford's Testimony Is Inadmissible on the Issue of Damages

Leaving aside whether such evidence is even relevant in an FCA case, Dey cannot meet its burden of demonstrating a reasonable probability that, had it reported truthful AWPs (consistent with Dr. Duggan's methodology), Medicare would have paid a higher dispensing fee, and that the "but for" dispensing fee can be quantified to a reasonable degree of economic certainty. *See Daubert*, 509 U.S. at 590 (1993) (stating that scientific knowledge requires "more than subjective belief or unsupported speculation").[7] Dr. Bradford's testimony therefore cannot be admitted as to damages. *See Marmo v. Tyson Fresh Meats*, Inc., 457 F.3d 748, 757 (8th Cir. 2006) ("Expert evidence is unreliable if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case.").

Dr. Bradford's opinion that Medicare would have increased dispensing fees had Dey reported lower AWPs is premised on two main assumptions. First, Dr. Bradford points to

[7] *See also Moberly v. Sec'y of Health and Human Servs*., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (stating that the "more likely than not" standard is not satisfied by proof of a "plausible" or "possible" causal link, but requires proof that meets the traditional tort standard of "preponderant evidence"); *Cf. Natchitoches Parish Hosp. Serv. Dist. v. Tyco Int'l, Ltd.*, 262 F.R.D. 58, 70 (D. Mass. 2008) ("Once plaintiff has made out a prima facie case '. . . sufficient to create an inference of reduced output and higher prices in the affected market . . . , the burden of production and proof then becomes defendant's, to show an efficiency explanation likely to undermine any inference that the exclusive-dealing arrangement results in lower output and higher market prices.'") (quoting XI Herbert Hovenkamp, *Antitrust Law* ¶ 1821 at 167).

congressional inaction as evidence that Medicare intended to pay inflated drug payments to cross-subsidize dispensing fees – specifically, to Congress's purported failure to adopt 1997 and 1998 proposals by the Clinton Administration to use actual acquisition cost instead of AWP (Report ¶¶ 244-245), and to Congress's suspension of CMS's "inherent reasonableness" authority to reduce payments for various items and services (*id*. ¶ 246). From this evidence, Dr. Bradford concludes, "Ultimately, the drug payments were the result of policy considerations often driven by the Congress that are independent of the published prices." *Id.* at ¶ 251. Second, Dr. Bradford infers that, but for manufacturers' reporting false AWPs, Medicare would have paid a dispensing fee of at least $33 for inhalation therapy drugs. He bases this opinion entirely on post-MMA dispensing cost studies prepared in 2004 and 2005 and the fact that CMS ultimately increased the dispensing fee.[8]

On the first point, Dr. Bradford, an economist, is not competent to draw inferences or conclusions from congressional action or inaction, an area in which he has no particular expertise. In any event, Dey is clearly proffering such testimony to provide a basis for a conclusion by the jury that a congressional failure to act must be interpreted to mean a government decision to approve the status quo. But legislative inaction can be indicative of many things other than acquiescence – including simple lack of agreement on a solution, lack of available alternatives, or a focus on other priorities. *See, e.g., United States v. Craft,* 535 U.S.

[8] Dr. Bradford does not expressly state that Medicare would have paid a particular dispensing fee in the "but for" world, and Dey states in its brief that "Dr. Bradford is simply critiquing Dr. Duggan's methodology and the implicit assumptions made by Dr. Duggan in holding all factors, such as dispensing fees, constant." Dey cannot avoid its burden of proof by characterizing Dr. Bradford's testimony as "simply critiquing" Dr. Duggan. If the considerations offered by Dr. Bradford are improperly speculative or founded on inadmissible legal opinion, they are not saved by their being criticisms of Dr. Duggan.

274, 287 (2002) ("congressional inaction lacks persuasive significance because several equally tenable inferences can be drawn from such inaction"); *Arnold Tours, Inc. v. Camp*, 472 F.2d 427, 437 (1st Cir. 1992) ("Congressional inaction frequently betokens unawareness, preoccupation or paralysis"); *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 502 (S.D. N.Y. 2009) ("To the extent that Exxon seeks to argue to the jury that it should infer from the federal government's inaction that the government somehow approved or condoned the use of MTBE, such argument is precluded"). Moreover, even were Bradford an expert on how this government makes decisions and solves problems, which he is not, his testimony is irrelevant. The jury should not be expected to draw conclusions about the significance of Congress's failure to adopt particular language in the Balanced Budget Act of 1997 (*see* Report ¶ 244), when this Act and its legislative history have already been evaluated in detail by this Court and the First Circuit. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 163-165 (1st Cir. 2009). Nor should the jury be permitted to determine whether Congress' suspension of CMS's "inherent reasonableness" authority regarding a wide array of medical items and services[9] supports an inference that Congress chose to pay inflated ingredient costs for inhalation therapy drugs. Dr. Bradford's testimony on these issues is unnecessary, unhelpful, and designed to invite the jury to read the legislative history relating to Medicare reimbursement differently than this

[9] The "inherent reasonableness" authority referenced by Dr. Bradford (Report at ¶¶ 256-257) was established in the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 390 (1997), codified at 42 U.S.C. § 1395u(b)(8)(A)(i), and could be applied to any of the "items or services" covered by Part B other than certain physicians' services paid under section 1848 of the Social Security Act. In 1999, Congress suspended the inherent reasonableness authority until after the Comptroller General issued a report on the use of the authority and the HHS completed subsequent rulemaking. Consolidated Appropriations Act of 2000, Pub. L. 106-113, § 223, 113 Stat 1501 (Nov. 29, 1999).

Court and the First Circuit already have. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 170 (ruling that Congress held an "unwavering commitment" to the "policy that Medicare reimbursement should be reasonable and reflective of acquisition costs").[10]

On the second point – that information generated during the post-MMA rulemaking proceedings must be taken into account – Dr. Bradford's testimony is based on speculation and is demonstrably unreliable. Dr. Bradford claims that if drug manufacturers had reported AWPs for inhalation therapy drugs within the parameters defined by Dr. Duggan, CMS would have increased the Medicare dispensing fee to $33.00 or more. Tellingly, Dr. Bradford cites to *no* pre-MMA studies. This is not surprising, as there is no factual evidence indicating that, *during the relevant time period*, HCFA or CMS studied dispensing costs for inhalation therapy drugs, possessed data showing that the $5.00 dispensing fee was inadequate, or even had a view on what types of costs a dispensing fee for inhalation therapy drugs should cover. Likewise, there is no evidence that HCFA/CMS ever declined to increase the dispensing fee because the agency thought ingredient cost reimbursement should cross-subsidize dispensing costs.[11] In fact, the available evidence indicates the opposite: that government officials established and maintained

---

[10] Dr. Bradford also points to Medicare's failure in 1991 to conduct invoice surveys to implement the "estimated acquisition cost" feature of the reimbursement regulation, 56 Fed. Reg. 59,621 (Nov. 25, 1991), promulgating 42 C.F.R. § 405.517(c) (1991) (Report ¶ 243). The inference Dr. Bradford offers this for – that Medicare deliberately declined to conduct such surveys because it wanted to pay inflated amounts for drugs – is baseless and pure speculation.

[11] *Cf. Testimony Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives*, Statement of William J. Scanlon Director, Health Care Issues (September 21, 2001) (GAO-01-1142T) (Reply Ex. 1 hereto) at p. 37 ("Medicare pays a dispensing fee of $5.00 for inhalation therapy drugs used with a nebulizer . . . . This fee was instituted in 1994. It is higher than dispensing fees paid by pharmacy benefit managers, which average around $2.00, and is comparable to many state Medicaid programs, which range from $2.00 to over $6.00.").

the $5.00 dispensing fee for reasons entirely unrelated to drug payments. Specifically, before 1994, Medicare paid no dispensing fee at all for inhalation therapy drugs because the dispensing costs were considered to be an overhead expense included in the DME payment for the nebulizer. *See* Reply Ex. 2 hereto. Likewise, there is also no evidence to suggest the $5.00 dispensing fee set in 1994 was based on considerations of cross-subsidization. *See* Reply Ex. 3.

With regard to Dr. Bradford's second point, the 2004-2005 rulemaking proceedings are not a reliable basis for concluding that Medicare would have increased the dispensing fee to $33.00 (or any other number) had manufacturers reported more truthful prices, for several reasons. First, the final agency decision to set a $33.00 dispensing fee was influenced by two reports submitted on behalf of the American Homecare Association, a report by the HHS OIG, and numerous public comments. *None* of this information existed before 2004. Indeed, all of the reports focused on costs of dispensing and levels of service in 2004 and after.[12] Moreover, the proceedings generated significant disagreement about what services and costs should be covered by a dispensing fee (e.g., medication compliance reviews, contacting physicians' offices, in-home

[12] Dr. Bradford selectively refers to several other studies, for instance a 2004 GAO finding that "the per patient cost of dispensing ranged from $7 to $204," and that suppliers reported using excess ingredient cost "payments to offer services that benefitted both beneficiaries and their physicians . . .' but were not required by Medicare." Report at 112, ¶ 239. Dr. Bradford neglects to note that the same report also found that suppliers reported using the excess payments "to market their services to physicians to gain market share." U.S. Government Accountability Office, "Medicare – Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs" (GAO-05-72, October 2004) at 4. Likewise, Dr. Bradford relies on a 2004 study by Muse & Associates to conclude that "the dispensing fee required to provide 2004 levels of service in 2005, under the ASP system, was $68.10 per HCPCS in a claim." *Id*. Dr. Bradford fails to mention that the HHS OIG found that Medicare beneficiaries often did not receive the services that formed the basis of the cost estimates in the Muse report, and that the Muse recommendations were not accepted by CMS. *See Review of Services Provided By Inhalation Drug Suppliers*, HHS OIG, OEI-01-05-00090 (September 2005); 70 Fed. Reg. 70116, 70227-70227 (Nov. 21, 2005) (Ex. 3 to U.S. Mem.).

visits, overnight delivery, patient instruction, sales and marketing, bad debt). To conclude that if manufacturers had reported lower AWPs at any time from 1994-2003, HCFA/CMS would have raised dispensing fees at all, much less to $33.00, is too speculative by far. There is simply no basis to infer, among other things, that data collection efforts equivalent to the AAH and OIG reports would have been undertaken by HCFA/CMS at that time; that the results of such data-gathering efforts would have been substantially similar as the results found in 2004-2005; and that agency decision makers would have made the same decisions regarding Medicare payments.

Dr. Bradford's opinion also ignores that the post-MMA dispensing fee changes were made in recognition of MMA-mandated reductions to drug payments (by switching from AWPs to ASPs)[13] *and* to DME payments for the nebulizers used to administer these drugs. Specifically, CMS was aware, *before* the MMA, that inhalation therapy providers received excessive payments for nebulizers, *see* 68 Fed. Reg. 50428, 50411 (Aug. 20, 2003), and Reply Ex. 4 (testimony of OIG Inspector General Janet Rehnquist). Notably, before the MMA, when in 2003 CMS proposed regulatory reductions in Medicare payments for inhalation therapy drugs (one option was to define AWP to mean the "widely available market price"), the agency brought attention to evidence of overpayments for the nebulizer equipment, it did not propose to change the payments for the nebulizer equipment *or* the dispensing fee, stating, "we do not expect any beneficiary access issues with payment at the widely available market price." 68 Fed. Reg. at

[13] Among other things, the MMA provided that, beginning January 1, 2005, payment for Part B drugs shall be at 106 percent of the manufacturer's average sales price (ASP), defined as the average price for all sales. Dr. Duggan's methodology assumes that, absent the false reporting, Medicare would have paid at 125 percent of Dey's average indirect sales price to the retail pharmacy class of trade.

50433. Subsequently, the MMA mandated significant reductions in nebulizer payments.[14] *See* 69 Fed. Reg. 47488, 47549 (Aug. 5, 2004) (noting that section 302(c)(2) of the MMA "requires a reduction in Medicare payment, beginning with 2005, for specified items of DME, including nebulizers paid under code E0570."). Only after these reductions did CMS propose to increase the dispensing fee. Any guess as to the amount by which the dispensing fee increase was responsive to reductions in drug reimbursement versus that for nebulizers would be just that – pure conjecture.

A recent Fourth Circuit opinion, *Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164 (4th Cir. 2010), illustrates the importance of the district court's gatekeeper function when expert opinions are based on speculation. There, insureds sued defendant insurance companies to recover the difference between actual billed charges and the allowed amount paid to providers. Defendants argued, relying on expert testimony, that damages should be offset "by the higher insurance premiums that plaintiffs potentially would have paid" had defendants reimbursed actual charges. The court rejected this argument, noting that the "proposed damages offset is too largely in the realm of speculation." Quoting from the trial court's opinion, the Fourth Circuit agreed that the increased premiums were "insufficiently certain" to justify offsetting damages:

> [T]he proposition that [defendants] can look back at their loss experience data, come up with how they would have increased their rates based on that loss experience data, proceed on the assumption that the South Carolina Department of Insurance would have approved the hypothetically requested rate increases

[14] Section 302(c)(2) of the MMA, entitled, "Payment Rule for Specified Items," amended Section 1834(a) of the Social Security Act (42 U.S.C. § 1395m(a)) to add a new subparagraph (21) which reduced payments for certain DME items, including nebulizers, that had previously been identified by the HHS OIG as being associated with significant overpayments to Medicare providers, as indicated in testimony before Congress on June 12, 2002 (*see* Reply Ex. 4 hereto).

> [as is required by law], and alter the premium payments under these insurance contracts is . . . speculative.

595 F.3d at 182-183.

The *Ward* case suggests that even if an expert could permissibly testify that, if a defendant had not engaged in the wrongful conduct, some indirect effect would have occurred to reduce the loss, such testimony is not helpful unless there is a competent, nonspeculative basis for quantifying the amount of the offset. Thus, if the *amount* of the alleged offset is too speculative to survive the Court's gate-keeping function, then testimony regarding the potential for such an offset is unhelpful to any issue before the jury. The only quantification that Dr. Bradford provides assumes without basis that during the entire period at issue (1995 - 2003), Medicare would have paid a dispensing fee at or greater than the level established in 2005 for 2006 and beyond (adjusted for inflation). The Court should exclude this, and all of Dr. Bradford's associated testimony, as unduly speculative.

II. DR. BRADFORD'S MEDICAID OPINIONS ARE INADMISSIBLE[15]

A. Testimony Concerning Encouragement of Generic Substitution

Dey defends Dr. Bradford's opinions about the Hatch-Waxman Act (¶¶ 22-26) on the ground that they provide "background" and "context." Dey Mem. 15. But this fails to acknowledge the obvious, namely, that Dr. Bradford wants the jury to conclude that the Hatch-Waxman Act reflects a congressional policy of encouraging generic substitution, and that the jury should factor this legislative policy into its consideration of the federal law governing the Medicaid program and Dey's conduct in reporting inflated AWPs. Report at pp. 10-11, ¶¶ 22-26.

[15] Should the Court grant plaintiffs' Motion to Bifurcate the Medicare and Medicaid claims for trial, decision on the remaining issues concerning Dr. Bradford's report could be deferred.

The implication of such testimony is that the law permits reporting inflated AWPs to encourage generic substitution. This goes far beyond mere "background." It is yet another effort to persuade the jury that federal law sanctions the conduct at issue.

Dey defends Dr. Bradford's opinions in paragraphs 31-35 of the Report on the ground that it is "an economic opinion" that describes a "mathematical consequence" that "percentage margins for generic drugs will generally be higher than those on brand-name drugs." Dey Mem. 16. Dey says that the government's criticisms should be left for cross-examination, and ignores what is stated in the Report and the arguments presented in the United States' brief, at 13-14. Those arguments demonstrate that exclusion of the testimony is warranted.

B. Opinions Concerning State Medicaid Programs and Cross-Subsidization

1. Dr. Bradford's "marginal pharmacies" and "accounting losses."

Dey's argument concerning Dr. Bradford's opinions about the "marginal pharmacy" and his calculated "accounting losses" consists primarily of an attempt to change the subject. The Court should not be fooled. Dr. Bradford states a legal conclusion that Medicaid's "equal access" provision[16] "implies that the marginal pharmacy is the focus of policy." Report at ¶ 107. Dr. Bradford opines that "[o]ne implication is that payments cannot be set based upon the average (or median) cost structure for state pharmacies." Dey does not reply to the government's argument that this opinion is flatly inconsistent with the law, *see* 42 C.F.R. § 447.301 (2006) (definition of "estimated acquisition cost"); Dey does not address the lack of evidence and speculative nature of Dr. Bradford's assertion that Medicaid programs intend to pay at the 95th

[16] *See* 42 U.S.C. § 1396a(30)(A); 42 C.F.R. § 447.204 (2009).

percentile (*see* U.S. Mem. 15-17[17]); and Dey does not respond to the observation that Dr. Bradford's calculation of "accounting losses" in connection with only the subject Dey drugs is inconsistent with his insistence that Dr. Duggan's model must be evaluated in its effects when applied to reimbursements for *all* prescription drugs (*see* U.S. Mem. at 18-19). Instead, Dey attacks Dr. Duggan's methodology for calculating alternative AWPs, and points to the fact that Dr. Duggan calculated the 95th percentile price. The fact that Dr. Duggan considered and rejected the 95th percentile price does nothing to validate Dr. Bradford's "marginal pharmacy" opinions.

In any event, Dey's attack on Dr. Duggan's methodology is unavailing. Dey asserts that Dr. Duggan's methodology would result in pharmacies switching Medicaid patients to higher-priced brands. Dey Mem. 19-20. The relevance of this to Dr. Bradford's "marginal pharmacy" opinions is unclear and illustrative of Dey's journey into speculation about secondary and tertiary effects of reporting more truthful AWPs. As pointed out in the government's brief (at 13-14), 41 states have mandatory generic substitution laws or policies, and the FUL program creates an incentive for pharmacies to dispense generics. The contention that Dr. Duggan's ASP+25% methodology would cause pharmacies to stop dispensing generic drugs is too speculative to pass muster under Fed. R. Ev. 402.

2. Dr. Bradford's cross-subsidization and "dispensing fee shortfalls."

Dr. Bradford opines that all states "chose" to pay the inflated AWPs, and that, if drug manufacturers had reported AWPs in accordance with Dr. Duggan's ASP+25% model, all states,

[17] Plaintiffs' brief pointed out that "[n]o state official and no Medicaid policy document states that Medicaid must overpay the ingredient cost of 95 percent of providers in order to ensure 'access' to the 'marginal' pharmacy." U.S. Mem. at 16-17. Dey's opposition does not challenge this.

throughout the relevant time period, would have paid higher dispensing fees at levels consistent with the dispensing costs for Massachusetts set forth in the 2007 Grant Thornton study.[18] Dey defends Dr. Bradford's cross-subsidization and dispensing fee shortfalls opinions by pointing to a few instances when states increased their dispensing fees in connection with a decrease in ingredient cost reimbursement. Dey Mem. 21-22. To conclude from this that price reporting at ASP+25% would have resulted in all states adopting dispensing fees in accordance with a data analysis that never existed until 2007, is simply too far-fetched to pass the *Daubert* gate. Dey does not dispute the evidence that in the great majority of instances when states have adjusted their payment methodologies to reduce ingredient cost payments, they have *not* made corresponding increases in dispensing fees.[19]

3. Dr. Bradford's Legal Analysis of a HCFA Appellate Board Ruling.

Dey does not defend Dr. Bradford's legal analysis about the significance of a 1991 HCFA Appellate Board ruling, U.S. Mem. at 22-23, and so this Court should exclude that testimony.

C. Opinions Concerning Payment Variation Across States and Use of Massachusetts As a Basis For Alternative Calculations

Dr. Bradford's opinions about variations in state methodologies and his conclusion that states could have chosen to use WAC but deliberately chose to pay inflated AWPs is nothing more than a disguised version of Dey's defense that government knowledge exonerates it of all

[18] Dey now says that Dr. Bradford applied the Massachusetts dispensing fee shortfall to all states "to be consistent with" Dr. Bradford's contention that all states could have chosen to use Dey's WAC prices. Dey Mem. at 22.

[19] Declaration of Mark G. Duggan, Ph.D in Support of Motion to Exclude Certain Testimony of W. David Bradford, Ph.D ("Duggan Decl.") (Ex. 4 to U.S. Mem.), Attachment A (Rebuttal Report).

liability for its inflated AWPs, as shown by Dr. Bradford's assertion that "all payments above that [Massachusetts payment] threshold can be viewed as choices made by individual states." Dey Mem. 23. An element-by-element analysis demonstrates why Dey's position lacks merit.[20]

Dr. Bradford's opinions are not relevant to falsity, and Dey does not argue to the contrary. Dey's brief defends Dr. Bradford's opinions on the ground that they are relevant to scienter and causation, Dey Mem. 23, but Dey fails to provide any supporting explanation. Whether Dey acted with "knowledge" or "reckless disregard" in reporting falsely inflated AWPs is not made more or less likely by Dr. Bradford's opinions on variation among state reimbursement methodologies or exchange of information among states on reimbursement issues. *See* Fed. R. Ev. 402. Nor is the "knowledge" element of FCA liability made more or less likely by Dr. Bradford's opinion that states deliberately chose to use AWPs. There is simply no logical connection. Similarly, whether Dey "caused" false claims to be submitted is not made more or less likely by such opinion testimony. Dey, not any state, reported false AWPs and caused pharmacy reimbursements to be inflated. Dey's apparent position – that state government policies were an intervening cause that absolves Dey of liability – should be rejected because it disregards federal regulatory law, disregards many state laws, and is unavailing for the reasons discussed above in connection with Dr. Bradford's Medicare opinions.

Dey does not contend that Dr. Bradford's opinions about state variations and using Massachusetts as a payment benchmark are relevant to damages, Dey Mem. 23, and rightly so, as any attempt to calculate damages for all states on the basis of one state's WAC methodology

[20] Dey incorrectly asserts that the government does not challenge Dr. Bradford's methodology. Dey Mem. at 23. Dr. Bradford's methodology is inadmissible for the same reason that his conclusions are. It is legally incorrect and irrelevant to any issue in the case.

would be the height of speculation and conjecture. Because Dr. Bradford's opinions are legally flawed, incorrect, and irrelevant to any issue in the case, they should be excluded.

CONCLUSION AND REQUEST FOR HEARING

For the foregoing reasons, the Court should exclude Dr. Bradford's testimony as specified above. The United States requests an evidentiary *Daubert* hearing on its motion, at which the United States will examine Dr. Bradford.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

/s/ Laurie A. Oberembt
Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: /s/ George B. Henderson, II
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

FOR THE RELATOR,

James J. Breen
Allison Warren Simon
The Breen Law Firm, P.A.
5755 Northpoint Parkway, Suite 260
Alpharetta, GA 30022
Tel. (770) 740-000

Gary Azorsky, Esq.
Susan Schneider Thomas, Esq.
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
(215) 875-3090

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: April 15, 2010

/s/ George B. Henderson, II
George B. Henderson, II